

S. 2852, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (Manager’s Amendment)
TITLE I: STRENGTHENING AND IMPROVING THE NATIONAL HEALTH SECURITY STRATEGY
Section 101: National Health Security Strategy
<ul style="list-style-type: none"> • Clarifies that the National Health Security Strategy should describe potential public health threats facing our nation and identify the processes to prepare to respond to such threats, consistent with other specified plans. • Incorporates into the Strategy— <ul style="list-style-type: none"> ○ A description of the current public health workforce and its capabilities to improve medical surge capacity. ○ Considerations for zoonotic disease and disease outbreaks related to food and agriculture. ○ Global health security and environmental hazards as they relate to domestic public health preparedness and response capabilities.
TITLE II: IMPROVING PREPAREDNESS AND RESPONSE
Section 201: Improving Benchmarks and Standards for Preparedness and Response
<ul style="list-style-type: none"> • Requires the evaluation of existing performance measures, benchmarks and standards for two core preparedness and response programs, the Public Health Emergency Preparedness (PHEP) cooperative agreement and the Hospital Preparedness Program (HPP).
Section 202: Amendments to Preparedness and Response Programs
<ul style="list-style-type: none"> • Reauthorizes the PHEP cooperative agreement through 2023. Clarifies that the PHEP cooperative agreement be administered through the Centers for Disease Control and Prevention and updates requirements for the plans required of all PHEP eligible entities. • Reauthorizes HPP through 2023.
Section 203: Regional Health Care Emergency Preparedness and Response Systems
<ul style="list-style-type: none"> • Requires the Assistant Secretary for Preparedness and Response (ASPR) to develop guidelines within two years, to inform regional systems of hospitals and health care facilities, to treat patients affected by chemical, biological, radiological, or nuclear (CBRN) threats, including emerging infectious diseases, and improve medical surge capabilities and capacity. • The guidelines will build on lessons learned from the Ebola virus outbreak in 2014 and will provide a roadmap for regions across the country to best leverage their health system infrastructure in the event of a bioterror attack, an emerging infectious disease outbreak, or a pandemic. • Allows the ASPR to develop and implement a demonstration project to put the new guidelines developed into practice in regions across the country, which sunsets in 2023. • Requires the Government Accountability Office (GAO) to report within three years on the progress made towards the implementation of the guidelines by hospitals and health care facilities, and requires subsequent recommendations to address challenges faced during implementation.

- Requires HPP grantees to report on implementation efforts aimed at meeting the capability guidelines.
- Incorporates into the National Health Security Strategy a coordinated and flexible approach to regional health care emergency preparedness and response.
- Encourages PHEP grantees to coordinate with regional health care emergency response capabilities.
- Prioritizes awarding HPP grants to entities that will enhance coordination among one or more facilities in a regional health care emergency system.
- Allows for additional resources authorized under HPP to go toward the new regionalized systems, ensuring existing resources are not taken away from HPP.

Section 204: Military and Civilian Partnership for Trauma Readiness

- Authorizes the Secretary, acting through the ASPR and in consultation with the Secretary of Defense, to award grants to trauma centers to enable military trauma teams to provide trauma care at such centers.
- Requires as a condition of such grants that military trauma providers providing care under such grants be allowed to deploy for military operations and to respond to public health emergencies.
- Integrates military trauma providers at such trauma centers into trainings and drills for public health emergencies.
- Calls for reporting to the Secretaries of HHS and Defense by grantees, as well as to Congress by the Secretaries of HHS and Defense.
- Authorizes appropriations through 2023.

Section 205: Public Health and Health Care Situational Awareness and Biosurveillance Capabilities

- Directs the GAO to conduct a study on federal spending for Centers for Disease Control and Prevention (CDC) activities related to facility development, and improved capacity and biosurveillance capability for responding to bioterrorism and other public health emergencies.
- Updates and improves CDC's biosurveillance capabilities to advance public health situational awareness by:
 - Updating the use of technical and reporting standards, including interoperability standards for data elements submitted to the biosurveillance network.
 - Improving coordination within Health and Human Services (HHS) and across federal agencies through the exchange of data in the biosurveillance network to better inform the situational awareness necessary to monitor, identify, and respond to CBRN threats.
 - Convening a public meeting for public and private stakeholders to improve the development and function of the biosurveillance network.
 - Updating the strategy and implementation plan for the biosurveillance network according to input from experts, and requiring the Secretary to submit such updates to Congress within two years.
 - Establishing an annual budget plan to ensure efficient and effective utilization of resources for the development and improvement of the biosurveillance network.

<ul style="list-style-type: none"> ○ Improving coordination with the intelligence community to ensure that the design and capabilities of the network align with the threats facing our nation. • Authorizes the Secretary to appoint up to 30 specialists at the CDC with expertise in capabilities related to biosurveillance, such as experts in informatics and data analytics. • Requires the GAO to evaluate and report on activities related to the development and improvement of the biosurveillance network and to provide subsequent recommendations. • Reauthorizes biosurveillance and situational awareness programs through 2023.
Section 206: Strengthening and Supporting the Public Health Emergency Fund
<ul style="list-style-type: none"> • To more immediately address the needs resulting from a public health emergency, improves the existing Public Health Emergency Fund (PHEF) by identifying key activities for which PHEF dollars may be used in the context of immediate support for the response activities for a public health emergency or prior to a potential public health emergency. • Requires the Secretary as well as GAO to conduct a review of the PHEF, including policies that may be needed to improve the PHEF (in the case of the Secretary) and the resources available in such fund and the ability to use such resources during a public health emergency (in the case of GAO).
Section 207: Improving Preparedness and Response to All-Hazards by Public Health Emergency Volunteers
<ul style="list-style-type: none"> • Further encourages states to develop and implement programs and policies to allow for the licensure of medical professionals to enable them to cross state lines during a public health emergency. • Clarifies that National Disaster Medical System, Medical Reserve Corps members, and individual practitioners are eligible to enroll in the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP). • Advises the Secretary to make public the ways in which states are waiving licensing requirements for health professional volunteers during a public health emergency in order to encourage state and individual participation in ESAR-VHP. • Reauthorizes ESAR-VHP through 2023.
Section 208: Clarifying State Liability Law for Volunteer Health Care Professionals
<ul style="list-style-type: none"> • Clarifies the application of state liability law for health care professionals who are members of the Medical Reserve Corps or included in the Emergency System for Advance Registration of Volunteer Health Professionals. • For such an individual providing health care services in a state with a public health emergency, under certain conditions, applies the liability laws of the state for which the emergency has been determined and in which the service is being provided. • Requires a GAO report on several aspects of health care providers credentialed by in the Emergency System for Advance Registration of Volunteer Health Professionals or state authorities.
TITLE III. REACHING ALL COMMUNITIES
Section 301: Strengthening and Assessing the Emergency Response Workforce

- Recent public health emergencies have strained the public health emergency workforce and have highlighted gaps in workforce preparedness. To address these challenges, this section:
 - Includes greater flexibility in pre-positioning response teams in advance of a public health emergency or potential public health emergency.
 - Requires a joint review of the National Disaster Medical System and an assessment of our medical surge capacity relating to the availability of public health workforce for both a widespread and multiple public health emergencies at one time.
 - Improves communication with Congress by requiring the Secretary to notify Congress when the NDMS workforce is insufficient to address a public health emergency, including information on the effect such insufficiencies will have and potential ways to address the issue.
 - Bolsters hiring authorities to allow for faster onboarding of NDMS to decrease the shortage in the health care emergency response workforce.
 - Extends death benefits for NDMS participants that are allotted to other public safety officers, including FEMA volunteers.
- Reauthorizes the National Disaster Medical System through 2023.
- Reauthorizes the Medical Reserve Corps through 2023.

Section 302: Health System Infrastructure to Improve Preparedness and Response

- Building off of lessons learned in previous public health emergencies, this section encourages the ASPR to coordinate with public and private-sector partners that provide critical supplies or information to an affected area during a public health emergency, to assist with the response.
- Requires the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to incorporate the need for certain medical supplies to be used with medical countermeasures (MCM) in MCM enterprise planning.
- Directs the Secretary to take into account manufacturing capacity and outside sources of medical supplies when replenishing products in the Strategic National Stockpile (SNS).

Section 303: Considerations for At-Risk Individuals

- Updates and aligns the term “at-risk individual” across the PAHPA framework to improve considerations, ensure consistency in considerations, and provide clarity throughout the framework.

Section 304: Improving Emergency Preparedness and Response Considerations for Children

- Codifies and continues the work of the Children’s Preparedness Unit at the CDC to ensure the needs of children are taken into consideration when preparing for and responding to public health emergencies.

Section 305: Reauthorizing the National Advisory Committee on Children and Disasters

- Updates the Advisory Committee on children and disasters to incorporate additional non-federal stakeholders and other improvements.
- Reauthorizes the Advisory Committee through 2023.

Section 306: Authorizing the National Advisory Committee on Seniors and Disasters
<ul style="list-style-type: none"> Establishes an advisory committee to evaluate and provide input and advice with respect to the medical and public health needs of seniors, as they relate to public health emergencies. Requires the Secretary to coordinate the activities and recommendations of the National Advisory Committee on Seniors and Disasters and the National Advisory Committee on Children and Disasters.
Section 307: Guidance for Participation in Exercises and Drills
<ul style="list-style-type: none"> Requires the Secretary to issue final guidance on the participation of federally funded public health personnel in drills and operational exercises for public health emergency preparedness and response.
TITLE IV: PRIORITIZING A THREAT-BASED APPROACH
Section 401: Assistant Secretary for Preparedness and Response
<ul style="list-style-type: none"> Clarifies the congressional intent for the ASPR to utilize experience related to biodefense and emergency preparedness and response. Encourages the ASPR to coordinate with the intelligence community, and defense and public health agencies in conducting his or her work to develop and strengthen our emergency preparedness and response framework.
Section 402: Public Health Emergency Medical Countermeasure Enterprise (PHEMCE)
<ul style="list-style-type: none"> Codifies the PHEMCE, an entity comprised of heads of relevant federal agencies to inform the direction of research, development and procurement of MCMs for the SNS, including considerations for deployment and distribution of MCMs.
Section 403: Strategic National Stockpile
<ul style="list-style-type: none"> Provides additional direction and a threat-based focus for the existing annual review of the SNS. Requires additional information on SNS procurement and replenishment decisions, as well as advanced planning for deployment, distribution, and dispensing for additions to the SNS. Requires GAO to review the Secretary's processes and decisions related to procurement of countermeasures for the stockpile and any changes in the federal organizational management of the SNS. Reauthorizes the SNS through 2023.
Section 404: Preparing for Pandemic Influenza, Antimicrobial Resistance, and Other Significant Threats
<ul style="list-style-type: none"> Provides authorities for the Director of the Biomedical Advanced Research and Development Authority (BARDA) to develop strategic initiatives for threats that pose a significant level of risk to national security. These strategic initiatives will accelerate and support advanced research, development, and procurement of countermeasures to address: <ul style="list-style-type: none"> Threats for which no countermeasure exists or which may become resistant to current countermeasures or existing countermeasures may be rendered ineffective.

<ul style="list-style-type: none"> ○ Threats that consistently exist or are continually circulating in a human or animal population and have significant potential to become a pandemic, such as pandemic influenza. ○ Certain threats resulting from exposure to a CBRN agent and which may present increased complications in treating a countermeasure resistant disease or condition during a public health emergency, including antimicrobial resistant pathogens.
Section 405. Reporting on the Federal Select Agent Program.
<ul style="list-style-type: none"> • Requires the Secretary to report on the implementation of recommendations from the Federal Experts Security Advisory Panel and the Fast Track Action Committee regarding improvements to the Select Agent Program.
TITLE V: INCREASING COMMUNICATION IN MCM RESEARCH AND DEVELOPMENT
Section 501: Medical Countermeasure Budget Plan
<ul style="list-style-type: none"> • Updates the Countermeasure Budget Plan to include considerations for manufacturing capabilities and capacity for MCMs, information on new and innovative technologies that may support the research and development of MCMs, and to improve the communication on areas of priority for MCM development.
Section 502: Material Threat and Medical Countermeasure Notifications
<ul style="list-style-type: none"> • Requires the Secretaries of HHS and Department of Homeland Security (DHS) to notify the Health, Education, Labor and Pensions Committee of the Senate, the Security and Government Affairs Committee of the Senate, and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives of current material threat determinations on an annual basis, and promptly notify Congress each time there is a change to such determinations. • Requires the Secretary to notify a manufacturer of a MCM within 90 days, regarding the Secretary's decision to replenish such MCM in the SNS at the end of its contract. • Requires the Secretary to provide written notification to MCM manufacturers for contracts that have been awarded, extended, or terminated.
Section 503: Availability of Regulatory Management Plans
<ul style="list-style-type: none"> • Requires FDA to post on the internet the processes and information necessary for potential MCM sponsors to apply for a regulatory management plan to raise awareness of the use of the plans for MCMs.
Section 504: BARDA and the Special Reserve Fund
<ul style="list-style-type: none"> • Reauthorizes BARDA through 2023. • Reauthorizes the BioShield Special Reserve Fund through 2023.
TITLE VI: ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES
Section 601: Administration of Countermeasures
<ul style="list-style-type: none"> • Clarifies BARDA's ability to use existing resources toward the development of technologies intended to assist in the administration of countermeasures.

Section 602: Medical Countermeasure Master Files
<ul style="list-style-type: none"> Establishes a clear process for submitting information and data on technologies into a Master File that may be incorporated into a future application to support a MCM product. A product sponsor, either the submitter of information or another person with right of reference, may utilize this information and data as a part of their MCM application, and build upon that data for future MCM applications. Requires the FDA to notify the Master File holder when the agency has referenced the technology in the Master File – clarifying that the same data and information can support future MCM applications.
Section 603: Priority Zoonotic Animal Drugs
<ul style="list-style-type: none"> Creates an expedited pathway for the development and review of animal drugs that treat animal diseases with the potential to transfer from animals to humans (zoonotic disease). At the request of the sponsor, the FDA may designate an animal drug as a priority zoonotic animal drug (PZAD) if preliminary clinical evidence indicates that the new animal drug has the potential to prevent or treat a zoonotic disease in animals, with the potential to cause serious or life-threatening diseases in humans.
Section 604: Animal Rule Report
<ul style="list-style-type: none"> Requires the GAO to consult federal agencies, manufacturers, and other biodefense stakeholders to inform a report within three years on the use of the animal rule in the development of MCMs, and if applicable make recommendations to support and speed the research and development of MCMs.
Section 605: Review of the Benefits of Genomic Engineering Technologies and their Potential Role in National Security
<ul style="list-style-type: none"> Requires the Secretary of HHS to convene a meeting with federal partners to discuss the potential role advancements in genomic engineering technologies (including genome editing technologies) may have in advancing national health security. Not later than 180 days after such meeting, the ASPR will issue a report detailing the discussion and providing recommendations to utilize innovation in this technology to advance national security.
TITLE VII: REAUTHORIZATIONS AND TECHNICAL CHANGES
Section 701: Reauthorizations and Extensions
<ul style="list-style-type: none"> Reauthorizes funding for VA medical facilities. Reauthorizes funding for influenza vaccine tracking and distribution during an influenza pandemic. Reauthorizes the temporary reassignment authority through 2023. Reauthorizes the MCM innovation partner through 2023, to align with the authorized timelines in this Act. Extends the limited antitrust exemption.
Section 702: Technical Changes

- Technical amendments to the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act.